**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	10600364
Filing Date	2003-06-21
First Named Inventor	Iris Chao (Zhao)
Art Unit	1633
Examiner Name	Dr. Janet Epps-Ford
Attorney Docket Number	

U.S.PATENTS

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OCT 19 2007
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First Named Inventor	Iris Chao (Zhao)
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PCT	1	1) Design Patent "Punch Device for Artificial Vessel", ZL200320113710.2, CN issued 02/23/2005. ABSTRACT The disclosure provided a punching device for making artificial vessel. The punch device is selected from a needle, cutter, laser, 2 phase solid-liquid lumen shaper, circular drill, and their combination thereof. The laser apparatus contains a single wave, made of an electrical stabilizer, a laser generator, a laser focus device, a transmission, a laser probe, and a laser beam focusing on a vessel wall, which is removed once opening an artificial	<input type="checkbox"/>
PCT	2	2) Utility patent application "Method and Device of Making Artificial Vessel" CN 2003101103312 pair filed 11/30/2003 now abandoned. * ABSTRACT Upon discovered new patterns (behaviors) of neovascularization, a material, device and method are induced to grow/culture artificial graft in situ. The new concept is based on blood flow's intending to search for another blood flow and endothelial cells' intending to follow the dynamic leading force of the blood flow to line over the blood	<input type="checkbox"/>
©	3	Lecture as Visiting Scholar for graduate students with International Award: "Reversed Bypass for Eye, Brain and Cardiovascular Ischemia" by Jin R. Zhao, in 3rd International Ophthalmologic Conference, Beijing, 11/11/2003: ABSTRACT Upon New Patterns (Behaviors) of New Vessel Formation found in Nebraska donated human tissues, a new method is induced to grow/culture artificial graft in situ. The system comprises a material, device, and method of making. The new concept is based on blood flow's intending to search for another blood flow and endothelial cells'	<input type="checkbox"/>
©	4	Lecture as Honorable Visiting Scholar for doctors and graduate students for clinical application: "Vessel Cultured in Situ for Eye, Brain and Cardiovascular Ischemia" by Jin R. Zhao at HeBei XingTai Eye Hospital, China, 3/2004: ABSTRACT As same as above. Clinical success and happy patients in HeBei related the method of culturing main artery in situ for femoral artery occlusion, reported Feb 2007.	<input type="checkbox"/>

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¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Not for submission under 37 CFR 1.99)

Application Number	10/600,364
Filing Date	2003/06/21
First Named Inventor	Iris Chao (Zhao)
Art Unit	1633
Examiner Name	Dr Jannet Epps-Ford
Attorney Docket Number	

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

- ☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

- ☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

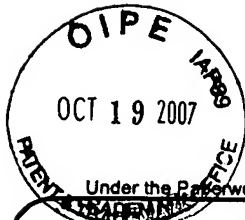
- ☐ See attached certification statement.
- ☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.
- ☐ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	Iris Chao (Zhao)	Date (YYYY-MM-DD)	2007-10-17
Name/Print	Iris Chao (Zhao)	Registration Number	

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**



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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	10/600,364
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First Named Inventor	Iris G. Chao
Art Unit	1633
Examiner Name	Janet L. Epps-Ford
Attorney Docket Number	

Sheet 1 of 3

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
		US- 5/908,029	06/01/1999	Knudson et al	p 6, column 2, line 54-67
		US- 5/645,587	07/08/1997	Chanda et al	p 4 column 1, line 31-37
		US- 4/098,571	07/04/1978	Miyata	p 11, column 1, line 31-37
		US- 5/968,093	10/ /1999	Kranz	p 7, column 2, Line 39-58
		US- 5/968,090	10/ /1999	Batcliff et al	p 9, column 1, Line 14-16
		US- 5/766,584	06/ /1998	Edelman et al	p 10, column 2, line 9-13
		US- 6/287,317	09/ /2001	Makower et al	p 29, column 1, Line 10, 27-31
		US- 5/624,437	04/ /1997	Freeman et al	p 7, column 2, Line 26-30
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁴
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				

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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language translation is attached.

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Information Disclosure Statement Form 8

Primary Examiner: Dr. Janet L. Epps-Ford /Art Unit 1633
Phone#: 571-272-0757, Fax#: 571-273-0757

Patent applications and lectures cumulative to Appn No. 10/600,364,
"Method, Material, and Device of Making Graft"

20

Paired Chinese Utility and Design Patent Applications filed same day by same inventor, Jin R. Zhao in Beijing, 11/30/2003. Both for PCT of Appn. No: 10/600,364.

1) Design Patent "*Punch Device for Artificial Vessel*", ZL200320113710.2, CN issued 02/23/2005.

30

ABSTRACT The disclosure provided a punching device for making artificial vessel. The punch device is selected from a needle, cutter, laser, 2 phase solid-liquid lumen shaper, circular driller, and their combination thereof. The laser apparatus contains a single wave, made of an electrical stabilizer, a laser generator, a laser focus device, a transmission, a laser probe, and a laser beam focusing on a vessel wall, which is removed once opening an artificial lumen. The laser probe includes a micro focusing to push the focus gradually. The goal is to make a lumen having a diameter from 8 microm (μ) to 3 mm. The new lumen contains two openings connected with the two different lumens from two side vessels. The device is easy to use, safe, and effective, which can not be induced from current vessel manufacture apparatus and material.

2) Utility patent application "Method and Device of Making Artificial Vessel" CN 2003101103312 filed 11/30/2003. *

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ABSTRACT Upon discovered new patterns (behaviors) of neovascularization, a material, device and method are induced to grow/culture artificial graft in situ. The new concept is based on blood flow's intending to search for another blood flow and endothelial cells' intending to follow the dynamic leading force of the blood flow to line over the blood flow to form a circuit. The 1st step of this method is making a lumen opening on a vessel wall to induce endothelial cells to spread out and thereafter, the 2nd step is making the wall in situ, which is reversed from tradition. The graft made thereof comprises a solidifiable adhesive fluid, suitable to form an extravascular solid bond and the final product is an artificial vessel. The device is selected from ice, laser, balloon, puncher, and needle. The embodiments include heart, brain, eye, shared tube, and vascular bypass. The vascular mode includes a reversed bypass from an artery to a vein

10 network. This system is also useful for repairing tubular gland, ureter, fallopian tube, and lymph duct.

* First CN OA 6/23/2006 cited CN 1199600A "Medical Laser for Cutting and Punching" published by Chinese Electrical Institute on 11/25/1998 and believed it meant the same. However, the application is reversed from traditional principle, and thus, no way to made it without the scientific discovery and creative work. Plus, there is no such device in the world with such treatment in hospital yet. Besides, the referral is for cutting and punching the heart muscle, which the disclosure did not get involved. The case is lost because I am here and can not carry it on.

* * * * *

Lecture as Visiting Scholar for graduate students with International Award: "Reversed Bypass for Eye, Brain and Cardiovascular Ischemia" by Jin R. Zhao, in 3rd International Ophthalmologic Conference, Beijing, 11/11/2003:

ABSTRACT Upon New Patterns (Behaviors) of New Vessel Formation found in Nebraska donated human tissues, a new method is induced to grow/culture artificial graft in situ. The system comprises a material, device, and method of making. The new concept is based on blood flow's intending to search for another blood flow and endothelial cells' intending to follow the dynamic leading force of the blood flow to line over the blood flow to form a circuit. The 1st step of this method is making a lumen opening on a vessel wall to induce endothelial cells to spread out and thereafter, the 2nd step is making the wall in situ, which is reversed from tradition. The graft made thereof comprises a solidifiable adhesive fluid, suitable to form an extravascular solid bond. The device is selected from ice, laser, balloon, puncher, and needle. The embodiments include heart, brain, eye, shared tube, and vascular bypass. The vascular mode includes a reversed bypass from an artery to a vein network. This system is also useful for repairing tubular gland, ureter, fallopian tube, and lymph duct.

Lecture as Honorable Visiting Scholar for doctors and graduate students for clinical application: "Vessel Cultured in Situ for Eye, Brain and Cardiovascular Ischemia" by Jin R. Zhao at HeBei XingTai Eye Hospital, China, 3/2004:

ABSTRACT As same as above.

Clinical success in HeBei used the method of culturing main artery in situ for femoral artery occlusion, reported Feb 2007. According to News on www.xg120.cn/info.asp, 110 cases improved and confirmed by angiography while 10 cases did not.

Prove US-10/600,364 claims patentability distinguishable from Referrals 1-4:

	Present application US-10/600,364	Ref.1: Nunez et al. WO 96/17633, 1996	Ref.2: Lim et al. US-3,774,615,	Ref.3: Bombard et al. US-2001/0007069	Ref.4: Murray et al. US-2002/0123805
Title	"Method, Material, and Device of Making Graft"	"Supplemented and unsupplemented tissue sealants (TS), methods of their production and use"	"Device for connecting or joining the ends of interrupted tubular organs in surgical operations without stitching"	"Tissue bonding system and method for controlling a tissue site during anastomosis"	"Biologic replacement for fibrin clot"
Utility Novelty	New artificial graft in situ	Fibrin Clot	Anastomosis		Fibrin Clot
	Making artificial tubular organ graft (bypass, connection) in situ having a lumen and wall	Fibrin sealant wound dressing	Anastomosis the ends of two interrupted existing tubular organs without stitching	Anastomosis of a target blood vessel with a graft (already made for use)	Repair intra/extra articular tissue including ligament, meniscus, cartilage, tendon, and bone
Claim	17-18: "Method of making an artificial graft comprising: i) making an opening on the wall of a tubular organ; through which ii) connecting the two lumens of two tubular organs through a device and said opening, wherein said device is coated by a solidifiable adhesive material joined to the adjacent tissue of said two lumens, and thereafter; iii) removing the device to leave a lumen that is connecting the two lumens of the two tubular organs. 19-26: "A solid-able adhesive nonpyogenic material" 27-30: "A removable device"	1-28, 32, 38: "A fibrin sealant wound dressing for treating wounded tissue ... expandable foam comprising fibrinogen in an amount capable of foaming a fibrin matrix in the presence of Factor XIII, thrombin and Ca++." 33-37, 39: "Method of preparing the fibrin sealant dressing." 29-31, 40: "Method of treating wounded tissue."	1-2: Device for stitchless connection or joining of the ends of interrupted tubular organs ... two connecting rings...elastic coupling member...said rings and clip....	0017. A method of performing an anastomosis between a target vessel and the end of a graft vessel. 1-13. A method of performing anastomosis comprising steps of: ...an elongated anvil and a graft vessel fixture (comprising clamping members each having one or more clamping surfaces adapted to compress the tissue on opposite sides.....;	1-5: "Method of treating an intra-articular injury by an arthroscopic procedure...comprising contacting the ends of a ruptured intra-articular tissue having an intrasy/novial environment...with a composition comprising soluble type I collagen, a platelet, and at least one of an extracellular matrix protein and a neutralizing agent."
Product	Novel artificial graft (Bypass, connection) cultured in situ Material for new use Device for new use	Wound dressing gel bandage ≈ natural clot	A device of two connecting rings and a fastening clip	40. Anastomosis system: Elongated anvil Fixture comprising clamping members	Methods of repairing article comprising fibrin clot composition.
Condition	No clot: Vivid blood flow through created opening Adhesive nonpyogenic material - 1 st fluid phase surround and join a body fluid to the adjacent tissue 2 nd solid phase support and seal the body fluid	Clot: Fibrinogen, Collagen, Ca++ (iron)	Two pre-existing interrupted tubular organs 2 Rings and a clip	Preexisting graft and target blood vessel Anvil Clamping Members	Fibrin replacement clot in ruptured article tissue